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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/339,153	06/24/1999	SI LOK	97-52D1	2249

7590 01/18/2002  
PAUL G LUNN  
ZYMOGENETICS INC  
1201 EASTLAKE AVENUE EAST  
SEATTLE, WA 98102

EXAMINER

KAUFMAN, CLAIRE M

ART UNIT	PAPER NUMBER
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1646

12

DATE MAILED: 01/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/339,153

Applicant(s)

LOK ET AL.

Examiner

Claire M. Kaufman

Art Unit

1646

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 04 January 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 1/4/02. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☒ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the \_\_\_\_\_ application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_

Claim(s) objected to: \_\_\_\_\_

Claim(s) rejected: 1-20

Claim(s) withdrawn from consideration: \_\_\_\_\_

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
10. ☐ Other: \_\_\_\_\_

Continuation of 5. does NOT place the application in condition for allowance because: The rejection of claim 20 under 35 USC 112, second paragraph, remains. Also, the rejection of claims 1-20 under 35 USC 101/112, first paragraph, remains. Applicants argue that a practical utility need not be a therapeutic or diagnostic utility, and that Zcytor11 polynucleotide has the practical utility of being useful for producing a homogenous population of cells expressing the encoded protein as evidenced by the Declaration under 37 C.F.R. 1.132 submitted by Dr. Jasper and attached exhibits. The Declaration by Dr. Jaspers has been entered and considered but does not overcome the rejection for the reasons discussed below.

The arguments has been fully considered, but is not persuasive. While a utility need not be therapeutic or diagnostic, it must be specific and substantial. The instant specification does not support such a utility for Zcytor11. If one does not know a specific or substantial utility for the protein, then cells expressing the protein likewise do not have utility. The argument that a homogenous population of cells, for example pancreatic cells, which express Zcytor11 is valuable as a research tool is not specific or substantial because until some actual and specific significance can be attributed to the protein identified in the specification as Zcytor11 or the gene encoding it, one of ordinary skill in the art would be required to perform additional experimentation in order to determine how to use the claimed invention. This additional experimentation is part of the act of invention and until it has been undertaken, Applicants' claimed invention is incomplete. It is not known what type of pancreatic cells which express Zcytor11 could be isolated, so there is no specific use for them. If the cells were, for example, exclusively insulin-producing pancreatic cells, then providing a protein for isolation of such cells might be substantial. However, this level of specificity is not disclosed. For the same reasons, the use of an antibody produced by immunization with the encoded protein does not have a specific or substantial use until a specific or substantial use for the protein it binds has been identified (see also second paragraph from the bottom on page 3 of the previous Office action (paper #9)).

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (703) 305-5791. Dr. Kaufman can generally be reached Monday through Thursday from 8:30AM to 12:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached at (703) 308-6564.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

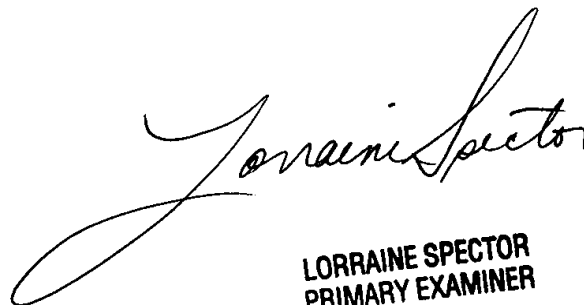
NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or applicant's representative. **NO DUPLICATE COPIES SHOULD BE SUBMITTED** so as to avoid the processing of duplicate papers in the Office. **Please** advise the examiner at the telephone number above before facsimile transmission.

Claire M. Kaufman, Ph.D.



Patent Examiner, Art Unit 1646

January 17, 2002



**LORRAINE SPECTOR  
PRIMARY EXAMINER**